REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 60-63 and 80-90 are pending in the subject application.

Claims 1-59, 64-79 and 91-100 were previously canceled.

Claims 60-63 and 80-90 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §112, second paragraph.

Claim 60 was amended for clarity and to more distinctly claim Applicant's invention.

Claims 87 and 88 were amended for clarity and to address the Examiner's non-art based rejections.

Claims 101 - 104 were added to more distinctly claim embodiments and aspects of the present invention.

The amendments to the claims are supported by the originally filed disclosure.

35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

Claims 87 and 88 stand rejected under 35 U.S.C. §112 on the grounds that there are antecedent basis, indefiniteness and/or vagueness concerns with the identified claims. The following addresses the rejections provided by the Examiner.

As provided above, claims 87 and 88 were amended to address the non-art concerns specifically identified by the Examiner. Applicants thus believe that the areas of rejection have been identified and addressed in the foregoing amendment.

It is respectfully submitted that for the foregoing reasons, claims 87 and 88 satisfy the requirements of 35 U.S.C. §112 and, therefore, these claims are allowable.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 60-63 and 80-90 under 35 U.S.C. §102(b) as being anticipated by Jumashev et al. [USP 4,059,115; "Jumashev"] or as being anticipated by Ulrich [USP 4,135,506]. Applicants respectfully traverse as discussed below.

Because claims were amended in the instant amendment, the following discussion refers to the language of the amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference. The following addresses the within rejections as to the following claim groupings.

CLAIMS 60-63

In claim 60, Applicants claims a method for stabilizing adjacent vertebrae of a spine. Such a method includes providing a cutting device including a rotating cutting implement having a midpoint and positioning a portion of the cutting device proximal a surface of the adjacent vertebrae and so that the midpoint of the rotating cutting implement is positioned opposite to the intervertebral space between the adjacent vertebrae. Such a method also includes rotatably cutting *a common channel at the same time in the adjacent vertebrae with the rotary cutting implement*. Such a method further includes inserting an implant into the common channel so that the implant extends between the adjacent vertebrae and through the intervertebral space, the space between the adjacent vertebrae. As indicated above, in the interests of advancing prosecution Applicants amended claim 60 in the foregoing amendment to provide that the rotating cutting implement is configured and arranged so as to rotate in a plane that is at an angle with respect to the surface of the adjacent vertebrae.

JUMASHEV

Jumashev describes a surgical instrument that includes a hollow elongated cylindrical body 1 with a handle 2 rigidly secured transversely thereto on the proximal end of the body 1.

Detachably secured on the distal end of the body 1 is a hollow cylindrical cutter 4 with a cutting edge 5, intended for simultaneous excision of two transplants in the shape of cylindrical segments from the bodies of two adjacent vertebrae. Situated in the body 1 and coaxially thereto is a shaft 6 with a knife 7 secured on its end. The knife 7 is secured by means of a spring plate 8, fastened by a screw 9 to the shaft 6, its lug entering a respective depression on the shank 10 of the knife 7. It is provided that the knife 7 maybe secured on the shaft 6 by means of a thread.

Basically, Jumashev describes a cutting device that utilizes what in other arts would be called a hole saw which is used to cut a cylindrical plug of material. In Jumashev, the cylindrical cutter 4 or hole saw, is positioned so it bridges two adjacent vertebrae. In this way, the cutting motion causes two transplants in the shape of cylindrical segments to be cut from the adjacent vertebrae. After so cutting the vertebrae using the hole saw, the knife is used to undercut the transplants so that they are thereafter removable.

It is clear from the foregoing that the cutter and methodology used in Jumashev is different from that of the present invention. In the present invention the rotating cutting implement cuts a common channel at the same time in the adjacent vertebrae. In contrast, Jumashev describes a process for excising two transplants that are in the shape of cylindrical segments. As shown in Fig. 18, the result of the described operation is the formation of a cylindrical hole in the adjacent vertebrae. Such a hole hardly corresponds to a channel.

Notwithstanding the foregoing and in the interests of advancing prosecution, claim 60 was amended to further provide that the rotating cutting implement is configured and arranged so as to rotate in a plane that is at an angle with respect to the surface of the adjacent vertebrae. Such an arrangement is physically impossible for the cutting device described in Jumashev.

ULRICH

Ulrich does not describe in any real detail a tool for cutting the vertebrae but rather describes the insertion of a pin into fractured vertebrae. Ulrich does describes that a non-straight hole is drilled in a vertebrae or between two vertebrae an specifically indicates that the non-

straight bore is formed in accordance with a related co-pending application that is identified in col. 1, ll. 7-10 of Ulrich.

In this regard, it also should be recognized that the bone pin described in Ulrich has a pair of ends, a bend between the ends, and at least one laterally extending lug at one of the ends. Ulrich also provides that such a pin has a pair of portions at either side of the bend. One portion is substantially straight and pointed, whereas the other portion is largely bent and extends generally perpendicularly to the one portion and is provided at its end with a pair of laterally extending lugs. These lugs extend in opposite directions to a plane including both of the portions of the pin, and are curved inwardly and formed with throughgoing holes so that they can easily be screwed to the side or front of the vertebra.

As to the method described in Ulrich concerning the use of the pin, it is further provided that a non-straight hole is drilled in a vertebra or between two vertebrae and the pin is inserted by means of a special forceps into this hole. It is further provided that thereafter the lug or lugs of the pin is screwed to the vertebra.

As can be seen from the foregoing, Ulrich does not describe a method for stabilizing adjacent vertebrae of a spine in which a portion of a cutting device having a rotating cutting implement having a midpoint is positioned proximal a surface of the adjacent vertebrae and so that the midpoint of the rotating cutting implement is positioned opposite to the intervertebral space between the adjacent vertebrae. Nowhere does Ulrich describe positioning the drill so that it is opposite to the intervertebral space. This is not surprising as none of the figures in Ulrich depict two adjacent vertebrae and the intervertebral space therebetween. Fig. 11 in Ulrich illustrates the bone pin set in a fractured vertebrae.

As also can be seen from the foregoing Ulrich does not describe a method for stabilizing adjacent vertebrae of a spine in which a common channel is rotatably cut at the same time in the adjacent vertebrae using the rotary cutting implement. Rather, Ulrich describes and teaches drilling a non-straight hole in the vertebrae, which is different from that claimed by Applicants.

Moreover, the drilling action described in Ulrich cannot correspond to the amended language of claim 60, which provides that the rotating cutting implement is configured and arranged so as to rotate in a plane that is at an angle with respect to the surface of the adjacent vertebrae. Namely an angle that is greater than 0 deg.

As the aperture drilled in Ulrich cannot correspond to the common channel as set forth in the claims, it also follows that Ulrich cannot describe inserting an implant into the common channel so that the implant extends between the adjacent vertebrae and through the intervertebral space, the space between the adjacent vertebrae.

In sum, Jumashev and Ulrich do not describe the methodology as set forth in claim 60. Moreover, there is no teaching or suggestion in either Jumashev or Ulrich that would suggest or teach the methodology of claim 60 or provide a motivation, suggestion or teaching to modify the respective disclosures so as to yield the claimed methodology.

As to claims 61-63, each of these claims depends (directly or ultimately) from claim 60. Thus, each of these claims is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Jumashev or Ulrich. In this regard, Applicants make the following further observations.

Claims 61 includes the further limitations that the cutting device is configured such that the rotating cutting implement is moveable between a first position where the rotating cutting implement is disposed within the cutting device and a second position in which a portion of the rotating cutting implement extends outside of the cutting device and that the step of rotatably cutting includes moving the rotating cutting implement to the second position so as to rotatably cut the common channel at the same time in the adjacent vertebrae.

The cylindrical cutter 4 in Jumashev is simply not inside another structure. Thus, Jumashev cannot describe the invention as set forth in claim 61.

As indicated above, the drilling apparatus is not described or disclosed anywhere in Ulrich. Thus, Ulrich cannot describe the invention as set forth in claim 61.

It is respectfully submitted that claims 60-63 are patentable over the cited reference for the foregoing reasons.

CLAIMS 80-86 & 89-90

In claim 80, Applicants claim a method for stabilizing adjacent segments of a mammalian bone. Such a method includes providing an arcuate implant member (a) having a length that is sufficient so the arcuate implant member extends between two adjacent bone segments, (b) having a cross-section sized so that portions of the arcuate implant member including ends thereof extend through a preformed aperture that is formed in each of the two adjacent bone segments, and (c) being configured so that the arcuate implant member lies in a plane as it extends between the adjacent bone segments and as the portions thereof extend through the preformed apertures. Such a method also includes implanting the provided arcuate fixation member so that (i) it extends between the adjacent bone segments, and (ii) so that the portions of the arcuate fixation member including ends thereof extend through the preformed apertures in each of the adjacent bone segments. In addition, the apertures formed in each of the two bone segments define an arcuate path in the plane and wherein the provided arcuate implant member is further configured so as to correspond to the arcuate path defined by the apertures.

As indicated above, in the discussion above regarding claims 60-63 and Jumashev, there are no through apertures or preformed apertures in the adjacent vertebrae in Jumashev. Jumashev describes a process where by a cylindrically shaped cutter is used to cut out cylindrically shaped segments from adjacent vertebrae such that a cylindrical shaped hole is in effect formed. It also cannot be said that the hole formed by the cutting operation defines an arcuate path in a plane and that the arcuate implant member is configured so as correspond to the arcuate path defined by the apertures.

As also indicated above in regards to Ulrich, while the hole made in the vertebrae is described as being non-straight, it is clear from the discussion regarding the pin that it is made up of two portions one of which is straight and pointed. The straight portion as shown in Fig. 11 in

Ulrich, traverse the fracture line in the vertebrae. Thus, then aperture in Ulrich is not arcuate, the pin is not arcuate. There also is no disclosure anywhere in Ulrich that the aperture formed in each of the two bone segments define an arcuate path in the plane in which the arcuate implant member lies as it extends between the adjacent vertebrae and further than the implant member is configured so as to correspond to this arcuate pathway.

In sum, Jumashev and Ulrich do not describe the methodology as set forth in claim 80. Moreover, there is no teaching or suggestion in either Jumashev or Ulrich that would suggest or teach the methodology of claim 80 or provide a motivation, suggestion or teaching to modify the respective disclosures so as to yield the claimed methodology.

As to claims 81-86 and 88-90, each of these claims depends (directly or ultimately) from claim 80. Thus, each of these claims is considered to be allowable at least because of their dependency from an allowable base claim. This shall not be considered an admission that these claims are not otherwise patentable over Jumashev or Ulrich.

CLAIMS 87-88

Applicants respectfully submit that the above remarks distinguishing claims 60 and 80 from Jumashev and Ulrich also at least applies to distinguish the method for stabilizing adjacent segments of a mammalian bone of claim 87 and the method for stabilizing adjacent segments of a mammalian bone of claim 88 from either of Jumashev and Ulrich. This shall not be considered an admission that these claims are not otherwise patentable over these references.

The following additional remarks shall apply to each of the above.

As the Federal Circuit has indicated, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913,

1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Applicants respectfully submit that it is clear from the following remarks that the above identified claims are not anticipated by either Jumashev or Ulrich.

It is respectfully submitted that for the foregoing reasons, claims 60-63 and 8-90 are patentable over either of the cited references and satisfy the requirements of 35 U.S.C. §102(b). Therefore, these claims are allowable.

CLAIMS 101-104

As indicated above, claims 101 - 104 were added to more distinctly claim embodiments of the present invention. These claims are clearly supported by the originally filed disclosure, including the originally filed claims. It also is respectfully submitted that these added claims are patentable over the cited prior art on which the above-described rejection(s) are based.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Director is hereby authorized to charge any deficiency in the fees

filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 49386 CON (305538).

Respectfully submitted,
Edwards Angell Palmer & Dodge, LLP

/ William J. Daley, Jr. /

Date: June 3, 2010 By: _____

William J. Daley, Jr.
(Reg. No. 35,487)
P.O. Box 55874
Boston, MA 02205
(617) 239-0100

Customer No. 21,874